

REMARKS

The present application contains claims 1-114, the status of which is as follows:

(a) Claims 1-50 have been canceled (claim 1 currently, and claims 2-50 by a previously filed preliminary amendment).

(b) Claims 51-94 are canceled.

(c) Claims 95-114 are new.

No new matter has been added.

The present patent application currently contains three independent claims: 95, 103, and 107.

The Applicant respectfully submits that claims 95 and 103 are in a condition for allowance, because they are of narrower scope than allowed and issued claim 1 of US Patent 6,148,232, which issued from US Application 09/189,170 (a parent application of the present patent application). Claim 95 of the present application is identical to claim 1 of the '232 patent, except for the added limitation that "the power source is adapted to apply an iontophoretic current to drive the substance into the skin." Claim 103 of the present application is identical to claim 1 of the '232 patent, except for the added limitation that passage of the substance is "by diffusion." These limitations find support in the parent applications as filed, as described hereinbelow.

Similarly, the Applicant submits that claim 107 is in a condition for allowance, because it is of narrower scope than allowed and issued claim 1 of US Patent 6,615,079, which issued from US Application 09/635,892 (a parent application of the present patent application). Claim 107 of the present application is identical to claim 1 of the '079 patent, except for the added step of "applying an iontophoretic current to drive the drug into the skin." This step finds support in the parent applications as filed, as described hereinbelow.

Claims 96-102, 104-106, and 108-114 depend, directly or indirectly, from claims 95, 103, and 107, respectively. These dependent claims are allowable because they are of narrower scope than the allowable independent claims from which they depend.

The respective limitations added to claims 95 and 107, as discussed above, find support in the specification of the parent applications as originally filed by at least the following:

Substance 132 typically comprises a conductive cream, gel and/or ink. In some applications of this embodiment, substance 132 additionally comprises a material which has a high diffusion coefficient into the skin and promotes the increased lateral component of the electric field relative to the perpendicular component, as described hereinabove. Alternatively or additionally, "pre"-iontophoresis, using a relatively weak electric field, is used to enhance the flow of substance 132 into the outer layer of the skin before application of the stronger electric fields which create the micro-channels. The presence of the conductive substance in the skin subsequent to the pre-iontophoresis is believed to increase the rate of micro-channel creation. Pre-iontophoresis is typically implemented by applying, for example, a 3 volt DC field between the electrodes for 30 seconds in order to drive substance 132 into the skin. Alternatively or additionally, a larger AC current which produces micro-channels is supplemented by a simultaneous small DC current which supports iontophoresis of substance 132 and thereby enhances micro-channel creation.

In some applications, when micro-channels are created in order to enhance transdermal delivery of an active substance, the active substance is preferably incorporated in substance 132 (col. 17, lines 1-24 of the '232 patent).

The limitation added to claim 103, as discussed above, finds support in the specification of the parent applications as originally filed by at least the following:

The term "micro-channel" as used in the context of the present patent application and in the claims refers to a pathway generally extending from the surface of the skin through all or a significant part of the stratum corneum, through which pathway molecules can diffuse. Preferably, micro-channels allow the diffusion therethrough of large

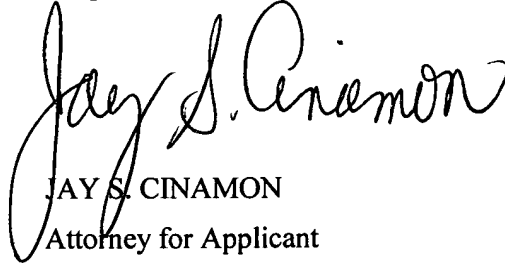
molecules at a greater rate than the same molecules would diffuse through pores generated by electroporation (col. 3, lines 3-10 of the '232 patent).

Claims 96-102, 104-106, and 108-114 are supported in the specification of the parent applications as originally filed at least as shown in the following table:

Claims	Support in the '232 patent
96, 104, and 108	"Preferably, the power source generates an electric field which causes a current to flow through the stratum corneum, and the device reduces power dissipated in the stratum corneum responsive to variation of a characteristic of the current" (col. 6, lines 60-64).
97-98, 105-106, and 109-110	"In a preferred embodiment, the power source generates alternating current, a frequency thereof being above about 100 Hz. Preferably, the frequency is between about 1 kHz and about 300 kHz" (col. 8, line 65 – col. 9, line 1).
99 and 111	"Prior to breakdown, the impedance between electrodes 120 is high, producing a generally large voltage drop therebetween, so the energy dissipated in the skin ( $P=VI$ ) has a desired high value. The energy dissipation rate is preferably sufficient to cause electrical breakdown of stratum corneum 100 in a short time, which is typically less than 50 milliseconds, but may range from about 1 to about 1000 milliseconds" (col. 15, line 62 – col. 16, line 2).
100, 102, 112, and 114	"Alternatively or additionally, 'pre'-iontophoresis, using a relatively weak electric field, is used to enhance the flow of substance 132 into the outer layer of the skin before application of the stronger electric fields which create the micro-channels" (col. 17, lines 7-11).
101 and 113	"Alternatively or additionally, a larger AC current which produces micro-channels is supplemented by a simultaneous small DC current which supports iontophoresis of substance 132 and thereby enhances micro-channel creation" (col. 17, lines 17-20).

Allowance of the claims in the present application is respectfully requested.

Respectfully submitted,

A handwritten signature in black ink, reading "Jay S. Cinamon". The signature is fluid and cursive, with the first name "Jay" and last name "Cinamon" clearly legible. The signature is positioned above the printed name and title.

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